



STATE OF WASHINGTON
WASHINGTON STATE BOARD OF HEALTH

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April 13, 2005

TO: Washington State Board of Health Members

FROM: Dr. Tom Locke, Board Chair

SUBJECT: HIV/AIDS RULES HEARING, CHAPTERS 246-100 AND 246-101 WAC

Summary and Background

Our understanding of HIV infection and social attitudes about HIV disease have changed significantly since the Legislature adopted the AIDS Omnibus Act in 1988 and the Board first adopted the associated rules. In response to the changing nature of the epidemic, the Washington State Association of Local Public Health Officials (WSALPHO) has asked the Board and the Department of Health (DOH) to review all statutes, rules, and policies related to HIV/AIDS and other blood borne infections such as hepatitis C. The agencies jointly initiated two related processes—one to review and update existing Board rules and the other to examine broader issues that may need to be addressed by the Legislature. The fundamental goals of the rule revision are to: (1) increase the proportion of HIV-infected persons who know their HIV status, (2) increase the proportion of persons exposed to HIV who are informed of that exposure, and (3) address the prevention and control of blood borne infections other than HIV.

In January, staff members from DOH gave the Board an overview of the rule revision processes and introduced some of the policy changes that have been proposed. Last month, representatives of the Governor's Advisory Council on HIV/AIDS (GACHA), Lifelong AIDS Alliance (LLAA), the Washington AIDSNet Council, and Planned Parenthood of Western Washington discussed areas of controversy within the proposed rule changes and the policy options for which they are advocating.

Today, the Board is scheduled to hold a public hearing on the proposed rule (attached) and consider adoption. Before we take public testimony, Jack Jourden and John Peppert of the Department of Health Infectious Disease and Reproductive Health Program will provide a brief review of the proposed changes and areas of controversy (see attached presentation). They will discuss the written public comments received and the Department's recommended responses (see attached comment summary). I have also attached a draft of the Significant Analysis on the proposed rule. Copies of comment letters will be available at the meeting.

Recommended Board Action

I recommend the Board consider, amend as necessary, and adopt the following motion:

The Board adopts the revisions to Chapters 246-100 and 246-101 WAC as published in WSR 05-06-12 except it shall be amended as follows:

- ***Add “explicitly” after “information,” and before “provide” in proposed sub-subsection 246-100-207(1)(b).***
- ***Insert “explicit” before “verbal or written” and delete “specific” before “consent in proposed sub-subsection 246-100-207(1)(c).***
- ***Fix incorrect references and minor drafting errors in proposed sections 203 and 206.***

Discussion

In December 2002, WSALPHO requested that the Board and DOH “consider a process to update policies, rules, and/or regulations concerning HIV/AIDS and other blood borne infections to reflect advances in the science of disease prevention and current best public health practices.” This resolution along with other reports and recommendations such as the *Washington State 2001 HIV Policy Summit* report, the *Washington State HIV Prevention Study Committee* report (March 2002), and the CDC Advancing HIV Prevention Initiative prompted the agencies to create two related processes—one to update existing Board rules and another to examine the full range of policy issues raised by changes in disease incidence, prevalence, treatment protocols, societal attitudes, and public health priorities and practices, including those issues outside the scope of current Board rules.

In September 2003, the Board and DOH initiated a review of the Board’s HIV-related rules, Chapters 246-100 and 246-101 WAC. The purpose was to explore ways to: (1) increase the proportion of HIV-infected persons who know their HIV status, (2) increase the proportion of persons exposed to HIV who are informed of that exposure, and (3) address the prevention and control of blood borne infections other than HIV. The process included soliciting input from the public through stakeholder meetings in Spokane and Tacoma and considering the content of reports and issue papers from various agencies and community-based organizations. Based on this review, DOH staff drafted changes to the WACs. These were vetted through several stakeholder meetings around the state and a CR-102 (attached) was filed.

Several policy issues were identified during the rule review process. Consent and counseling requirements were seen by many to be barriers to HIV testing. Counseling requirements were regarded as burdensome and did not allow for a client-centered approach. Many people misunderstood the consent requirements and thought that written informed consent was required before testing. New testing methods and technologies were not included in the existing regulation. Conflicting opinions emerged over the purpose and value of requiring that individuals be informed of the availability of anonymous HIV testing. The rule review also found that the rules related to partner notification and referral services lacked adequate standards and placed the primary responsibility of contacting partners of HIV-positive individuals on health care providers and patients, who often lack the skills and resources to successfully carry this out. Another policy issue related to the critical need to promote educating HIV-positive individuals about transmission of HIV to others.

DOH staff described the proposed WAC changes at the January 2005 Board meeting. A panel discussed remaining areas of controversy at the March 2005 meeting. Although consensus has been achieved on a broad range of revisions to the current rule, areas of disagreement still remain. They include:

Partner notification: The proposed rules presume that local public health personnel who are trained and experienced with providing partner contact and referral services (PCRS) will provide partner notification in most instances. The American Civil Liberties Union (ACLU) believes that in most cases this should be performed by the person with HIV or that person and his or her medical provider. LLAA has proposed

language that would clarify that a local health decision to pursue PCRS should be supported by consultations with the client and provider. The ACLU and LLAA comments fundamentally misunderstand how PCRS works in practice. Partner notification is very difficult and stressful. To be successful, it takes the assistance of highly skilled professionals. Most primary care practitioners feel that they lack the time and training to assist with this essential service. The Washington State Medical Association has passed a resolution formally asking for the changes in PCRS that are present in the draft rule.

Partner notification is always voluntary; no one can be coerced to reveal their sexual or needle-sharing contacts. Successful partner notification requires that a person newly diagnosed with HIV place their trust in the person who will be assisting with partner notification. Public health professionals are specifically trained to earn patient trust by working through the difficult issues that surround partner notification. Partner notification strategies need to be individualized to fit the unique circumstances of each client's personal history and to protect each client's confidentiality. The current rule lacks this flexibility and has placed this very difficult task on people who feel ill prepared to deal with it. The result is that far too many sexual and needle-sharing contacts of HIV cases never know they have been exposed to HIV. This lack of notification leads to delayed diagnosis and increased transmission of HIV. The draft rule incorporates what we have learned over the last 17 years about improving partner notification. It encourages physicians, patients, and public health professionals to work out a joint strategy for notifying partners and ensuring appropriate HIV testing. Patients will continue to directly notify those whom they wish to; physicians can continue to play a central role, if they are so inclined. And of vital importance, public health professionals will bring their proven expertise in PCRS to this difficult task to assure patient confidentiality is preserved and exposed partners are given potentially life saving information.

Consent: Several commenters proposed that the rules should require separate written consent (Saxman, LLAA, ACLU). Informed consent is the goal. Testing for HIV (or anything else) without informed consent is illegal. Written consent is not required by the current Board rule, but it is standard practice in many clinical settings. This good practice will most likely continue in many clinics, but the new language would clarify that a range of options is available. The Board should not be limiting options when prescriptive requirements may create barriers to testing in some settings. The proposed rules would make the consent standard for HIV the same as for other medical tests and procedures. GACHA has proposed language that would specify that the consent for HIV testing be explicit. "Explicit" and "specific" have very similar meanings in this context. Webster's primary definition of "explicit" is: "Not implied merely, or conveyed by implication; distinctly stated; plain in language; open to the understanding; clear; not obscure or ambiguous; express; unequivocal; as, an explicit declaration." As such, explicit is an appropriate term to use to fulfill the statutory requirement that persons being tested for HIV infection are making an informed decision to consent to that diagnostic testing.

Anonymous testing: Several commenters proposed that providers be required to inform clients about the availability of anonymous testing and the difference between anonymous and confidential testing. This is in the current rule. The proposed rule requires it "as appropriate," allowing medical providers to use their professional judgment. Like separate written consent, mandatory counseling about anonymous testing sends a confusing and mixed message to a person considering HIV testing, encouraging distrust and second thoughts about the testing. Doubts that cause delays in testing or encourage denial about HIV risk can have life threatening consequences. From a medical and public health perspective, anonymous testing is inferior to confidential testing. It makes it impossible to notify clients who fail to return to receive their test results. Nationally, 30 percent of people who undergo anonymous testing fail to return for their test results. A primary goal of the HIV rule revision is to assure that more people know their HIV status. This requires not only testing but also the assurance that people receive their test results. Anonymous testing is inappropriate in the context of a personal relationship with a trusted health care provider. In such a

setting, confidentiality is well protected by existing state and federal laws as well as professional ethics. Anonymous testing is appropriate in settings where a trusting relationship does not exist or when a person is so fearful of HIV testing that they are unwilling to have a confidential test performed. New rapid HIV testing technologies that give a result in 20–40 minutes are an important advance in assuring that everyone who undergoes anonymous testing knows their test results. Clients are free to pursue anonymous testing from a variety of sources. While this option should certainly be preserved, it should not be the responsibility of private physicians to promote anonymous testing when they feel it is medically inappropriate. The draft rule removes this mandate while preserving access to anonymous testing.

Destruction of records: Some commenters have objected to language allowing local health jurisdictions to retain partner counseling and referral services records beyond 90 days if they are being used for an active investigation of behaviors endangering others or behaviors presenting an imminent danger (BPID). Some have asked for a more explicit definition of “active” and/or an upper limit on retention time (GACHA, LLAA, Sexson) while others (ACLU) have argued that information collected for one purpose (PCRS) should not be used for a secondary purpose (behaviors endangering investigations). Most of these comments misunderstand the very specific language of the draft rule. Washington State law (RCW 70.24.022 or 70.24.024) require that health officers investigate credible reports of people who are exposing others to sexually transmitted diseases (including HIV) without informing them of their exposure risk. These investigations can stretch over many months as information is gathered. On rare occasions, a person newly diagnosed with HIV infection will report a sexual or needle-sharing partner who is the subject of such an investigation. If this occurs, it is evidence of conduct endangering public health, such as the willful exposure of a person to HIV without their knowledge, and is highly relevant to the investigations required by RCW 70.24.

The current rule language conflicts with a health officer’s statutory duties to investigate and address these dangerous behaviors by forcing the destruction of evidence of unsafe and illegal behaviors. The draft rule reconciles this conflict without abandoning Washington’s “names to codes” hybrid reporting system. Some of the concerns raised about the conflicting responsibilities of health officers have merit. These concerns cannot be effectively addressed through a rule revision, however, and will require fundamental legislative changes to Washington’s highly prescriptive HIV laws.

The overarching goal of this WAC revision is to reduce barriers to HIV counseling and testing. This will result in increased testing, earlier diagnosis, earlier treatment, and reduced transmission. Highly prescriptive counseling standards, separate written consent, the need for untrained clinicians to provide PCRS, and mandatory education about anonymous testing are all identified barriers to expanded testing by primary care physicians. The draft rule addresses all of these issues. The Washington State Board of Health is entrusted with responsibilities that have life and death consequences. Revision of the Board’s HIV rules is one such responsibility. We are currently losing the battle to reduce HIV transmission in Washington State. Part of the problem is that the well intentioned rules the Board adopted in 1988 have created barriers to routine HIV testing and reliable systems for notifying and testing people who have been exposed to HIV. The Board now has the opportunity to remove these barriers and, in doing so, fulfill our most important mission—to protect and improve the health of Washington’s citizens.

Attachments